Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

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Summary of the Risk Assessment and Risk Management Plan (Consultation Version) for Licence Application DIR 193

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application (DIR 193) for transport, storage and disposal of a genetically modified (GM) vaccine against infectious laryngotracheitis virus (ILTV), as part of its commercial supply as a vaccine for chickens. These activities are classified as Dealings involving the Intentional Release (DIR) of genetically modified organisms into the Australian environment under the *Gene Technology Act 2000*.

Before the GM vaccine can be used, Bioproperties Pty Ltd must also obtain regulatory approval from the Australian Pesticide and Veterinary Medicines Authority (APVMA). The APVMA administers the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) to regulate agricultural and veterinary chemical products, including veterinary vaccines. For commercial products, the normal form of approval is through registration. The APVMA can impose conditions on the use of veterinary products via registrations and permits.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed supply of the GM vaccine poses negligible risks to human health and safety and negligible to low risks to the environment. Licence conditions have been drafted for the proposed supply. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

The application

Application number	DIR-193
Applicant	Bioproperties Pty Ltd
Project title	Commercial supply of a genetically modified vaccine against infectious laryngotracheitis virus in chickens[1]
Parent organism	Infectious laryngotracheitis virus (ILTV)
Introduced gene and modified trait	Deletion of gene encoding glycoprotein G, which reduces ability of virus to cause disease
Previous releases	The GM vaccine has been previously approved for field trials to vaccinate broiler chickens against ILTV in selected chicken farms in rural Victoria and New South Wales.
Current approvals	The GM vaccine is currently not approved for commercial supply in any region or country.
Proposed locations	Australia-wide

[1] The title for the licence application submitted by Bioproperties Pty Ltd is “Commercial supply of Vaxsafe ILT”.

Primary purpose	Commercial supply of the GM vaccine against ILTV in chickens.

Risk assessment

The risk assessment concludes that risks to the health and safety of people are negligible and the risks to the environment from the proposed supply of this vaccine are negligible to low. Specific risk treatment measures are included in the licence to manage these low risks.

The risk assessment process considers how the genetic modification and activities conducted with the GM vaccine in the context of transport, storage and disposal might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account information in the application, relevant previous approvals, current scientific knowledge and advice received from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP. Both the short and long term risks were considered.

Credible pathways to potential harm that were considered include; the potential exposure of people to the GMO; the potential exposure of animals to the GMO; and the potential for the GMO to recombine with other similar viruses. The potential for the GMO to be released into the environment and its effects were also considered.

The principal reasons for the conclusion of negligible to low risks associated with transport, storage and disposal of the GMO are:

- The GMO has a limited host range, is attenuated and unlikely to cause disease in chickens or other susceptible bird species;
- Infectious laryngotracheitis virus does not cause disease in humans or other organisms except some susceptible bird species;
- The likelihood of accidental exposure to the GMO by people and the environment would be minimised due to well-established transport, storage and disposal procedures that are regulated by each State and Territory; and local councils;
- The GMO would need to be registered with the APVMA, who would impose conditions on the use, transport, storage and disposal of the vaccine; and
- Complementation and recombination of the GMO with another alpha herpesvirus is possible but since the ILT virus was isolated in Australia, similar genetic material would already be present in the environment.

Risk management

The risk management plan concludes the identified negligible to low risks can be managed to protect the health and safety of people and the environment by imposing risk treatment measures. Licence conditions are proposed to prevent the concurrent administration of vaccine with any other ILTV strains and restrict the vaccination to healthy birds. Additional general conditions were also included to ensure that there is ongoing oversight of the GM vaccine.

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks and considers general risk management measures. The risk management plan is given effect through licence conditions.

As the risk of recombination leading to novel ILTV strains was assessed as negligible to low, specific risk treatment measures, such as vaccination of only healthy chickens and no concurrent use of live ILTV vaccines were included in the draft licence to ensure that the risk is managed. In addition, draft licence conditions include post-release review (post-market surveillance) to ensure that there is

ongoing oversight of the supply of the GM ILTV vaccine and to allow the collection of information to verify the findings of the RARMP. The draft licence, detailed in Chapter 4 of the consultation RARMP, also contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements, which include an obligation to report any unintended effects.